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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,297	04/14/2005	Hakan Moller	027651-266	6310

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EXAMINER	
JOYNER, KEVIN	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
03/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,297	MOLLER ET AL.	
	Examiner	Art Unit	
	KEVIN C. JOYNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 26-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2007 has been entered.

Drawings

2. The drawings were received on May 9, 2007. These drawings are accepted.

Specification

3. The amendments to the specification were received on November 13, 2007. These amendments are accepted.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-6, 8-14, 16-19, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina et al. (U.S. Publication No. 2002/0129915) in view of Watling et al. (U.K. Patent Application No. GB 2354443 A).

Zelina discloses a device for sterilization in production of packages which is adapted for sterilization with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process, said device comprising a heating zone (170) a sterilization zone (11) and a venting zone (182) as shown in Figure 8, an ambient temperature sensor (152) that is capable of sensing the ambient temperature outside the device as shown in Figure 1, a concentration meter (153) that is capable of measuring the concentration of sterilizing agent in the sterilization zone as shown in Figure 8, and a first control unit (150) for controlling the amount of sterilizing agent introduced in the sterilization zone based on the temperature measured by the ambient temperature sensor and the concentration measured by the concentration meter as disclosed in paragraph 57. Zelina does not appear to disclose that the temperature sensor is located outside the device and a relative humidity sensor for measuring the relative humidity outside the device. Watling discloses a device (10) for sterilization of packages wherein the device comprises a controlled loop with ambient temperature and relative humidity sensors (14) located outside of the device in order to provide a recirculating system that does not require the steps of removing water vapor and sterilizing gas mixtures during the critical sterilization phase of the cycle on page 4 and Figure 1. Watling continues to disclose that a condensation meter (16) is provided and in communication with a control unit that is capable of sending a signal to control the

temperature and/or flow of hot air in a gas production unit which produces the sterilizing agent (concerning claim 41; abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide relative humidity and ambient temperature sensors located outside of the device in order to provide a system that does not require the steps of removing water vapor and sterilizing gas mixtures during the critical sterilization phase as exemplified by Watling. It would have also been obvious to one of ordinary skill in the art at the time of the invention to utilize a condensation meter in communication with a separate control device in the apparatus of Zelina in order to ensure an appropriate amount of condensation occurs inside the device as exemplified by Watling.

In regards to claim 3, Zelina continues to disclose that the device further comprises a package heating temperature sensor that is capable of sensing the temperature of the packages before entry into the sterilization zone as disclosed in paragraph 59. More specifically, the paragraph discloses that in an alternate embodiment the temperature of the individual containers are measured if the process cannot control the temperature of the incoming containers accurately. Therefore, the sensor of the alternate embodiment provides a sensor that is fully capable of measuring the temperature of the packages before entry into the sterilization zone.

Concerning claim 4, the device further comprises a feedback circuit that is capable of controlling the heating in the heating zone based on the temperature of the packages as disclosed in paragraphs 57 and 58.

Regarding claim 5, the reference continues to disclose that the device comprises a condensation detector that is capable of detecting condensation in the sterilization zone as disclosed in paragraph 59. Concerning claim 8, the reference also teaches that the gaseous sterilizing agent is hydrogen peroxide in paragraph 14. In regards to claim 10, the reference teaches that the device sterilizes the packages before filling the packages with said packages having an open end and a closed end as shown in Figure 8.

Concerning claim 6, the device further comprises a means for maintaining a higher pressure in the sterilization zone than in the heating zone and venting zone. More specifically, the venting zone has a vacuum pump that creates a negative pressure in that zone, thus creating a means for maintaining a higher pressure in the sterilization zone than in the venting zone. The sterilization zone has fill lines (172) that supply vapor to the sterilization zone causing a positive pressure in that zone. Since there is no source of positive pressure in the heating zone as shown in Figure 8, then the sterilization zone comprises a means for maintaining a higher pressure in the sterilization zone than in the heating zone. Regarding claim 9, the reference continues to disclose that the packages are subjected to filling (paragraph 65)

Regarding claim 10, Zelina continues to disclose that the heating zone comprises means (171) that is capable of heating the packages to a temperature above a dew point of the sterilizing agent used in the sterilization zone as disclosed in paragraph 62.

Concerning claim 11, the reference also discloses that the venting zone comprises means that is capable of venting away the sterilizing agent used in the

sterilization zone from the packages after sterilization as disclosed in paragraphs 64 and 65.

Concerning claims 12 and 13 and 38, the reference continues to disclose that the device comprises means for controlling a flow of gaseous sterilizing agent in the sterilization zone, such that the gaseous sterilizing agent flows essentially in a direction from the open end of the packages toward the closed end of the packages as well as introducing the gaseous sterilizing agent with nozzles in a top portion of the sterilization zone and evacuating the sterilizing agent in a bottom portion of the sterilization zone, and maintaining a flow of gaseous sterilizing agent essentially from top to bottom as disclosed in paragraph 63.

In regards to claim 14, the reference also teaches that the device comprises a means for controlling the venting air flow in the venting zone such that the venting air flows essentially in a direction from the open end of the packages toward the closed end of the packages as shown in Figure 8 and disclosed in column 65. Concerning claim 16, the reference teaches that the device is fully capable of sterilizing itself internally. More specifically, the hydrogen peroxide and the heaters in the sterilization and heating zones will not only sterilize the bottles themselves but also the area around the bottles and the structural parts inside zones. Regarding claims 17 and 18, the reference teaches that the device comprises means (171) for heating the interior of the device and a unit (10) for production of the gaseous sterilizing agent as shown in Figure 8. Regarding claim 19, Zelina continues to disclose that the device comprises a filling zone (190) for filling packages and means for maintaining a higher pressure in the filling zone

than in the venting zone. More specifically, the filling zone (190) operates under an ambient pressure and the venting zone (182) operates under a negative pressure from the exhaust line (182) and the vacuum pump (184). Thus, the exhaust line and the vacuum pump is a means for maintaining a higher pressure in the filling zone than in the venting zone.

6. Claims 2, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Watling et al. (U.K. Patent Application No. GB 2354443 A) as applied to claims 1, 3-6, 8-14 and 16-19 above, and further in view of Taggart (U.S. Publication No. 2001/0000558).

In regards to claim 2, Zelina in view of Watling is relied upon as set forth above. Zelina in view of Watling does not specifically state that the device comprises a package start temperature sensor for sensing the temperature of the packages entering the heating zone. Taggart discloses a device for sterilization in the production of packages with a sterilizing agent, said device comprising a sterilization zone (zones 60 and 116) and a heating zone (152). The reference continues to disclose that apparatus comprises a temperature start sensor (H) that is capable of sensing the temperature of the packages entering the heating zone as shown in Figure 16. More specifically, two temperature sensors are located in the heating zone (152). Each sensor is located at one end of the zone as shown in Figure 16. The packages move through the apparatus from left to right in Figure 16 (paragraphs 46 and 47). The sensor on the left side is fully capable of sensing the temperature of the packages entering the heating zone because of its position in the zone. Therefore, it would have been obvious to one of ordinary skill

in the art at the time of the invention to modify the apparatus of Zelina in view of Watling to include a temperature sensor for sensing the temperature of the packages entering the heating zone to control the process as efficiently and effectively as possible as exemplified by Taggart.

Concerning claim 7, Zelina in view of Watling is relied upon as set forth above; wherein the reference continues to disclose that the device contains HEPA filters in between each zone to deter any cross contamination as disclosed in paragraph 65. However, Zelina does not specifically disclose that the partitionings (referenced as HEPA filters) have openings for the passage of the packages. Taggart discloses a device for sterilization in the production of packages with a sterilizing agent, said device comprising a sterilization zone (zones 60 and 116) and a heating zone (152). The reference further discloses that the zones are separated from each other by means of partitionings having openings for the passage of packages to control the flow of sterile air throughout the apparatus (paragraphs 64-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zelina in view of Watling to include partitionings having openings between each zone to permit the passage of packages and control the flow of sterile air as exemplified by Taggart.

7. Claims 15 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Watling et al. (U.K. Patent Application No. GB 2354443 A) as applied to claims 1, 3-6, 8-14 and 16-19 above, and further in view of Niwa (U.S. Publication No. 2001/0000558).

Concerning claims 15, 38 and 42, Zelina in view of Watling is relied upon as set forth above, wherein the reference further discloses a means (186 and 188) for controlling the flow of venting air arranged to introduce the venting air in a top portion of the venting zone, and maintaining a flow of venting air essentially from top to bottom as shown in Figure 8. Zelina in view of Watling does not appear to disclose that the air is evacuated in the bottom portion of the venting zone. Niwa discloses a device used in the production of packages wherein the devices comprises a plurality of chambers each consisting of fluid inlet and outlets as shown in Figure 1. The reference further discloses that each chamber comprises separate inlet nozzles that are located in the top portion thereof, and outlet nozzles that are located at the bottom portion thereof. The outlet nozzles are provided in the bottom portion of the chamber in order to evacuate any unwanted gas that may be present in said chamber by utilizing the effects of gravity (column 9, lines 7-45). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zelina in view of Watling to evacuate the air in the bottom portion of each zone in order to utilize the effects of gravity and efficiently remove any unnecessary components away from the sterilized packages. Concerning claim 39, the outlet of Zelina is provided with a catalyst unit in fluid communication with the sterilization zone for degrading the sterilizing agent drawn from said sterilization zone (paragraph 51; Figure 1). Regarding claim 40, the controller of Zelina controls the operation of the unit for production of the gaseous sterilizing agent (paragraph 57).

8. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Watling et al. (U.K. Patent Application No. GB 2354443 A) and Niwa (U.S. Publication No. 2001/0000558) as applied to claims 1, 3-6, 8-14 and 16-19 above, and further in view of Shibauchi et al. (U.S. Patent No. 4,979,347).

Regarding claims 36 and 37, Zelina discloses that the heating zone comprises heaters in the top portion of the heating zone in order to heat said objects (Figure 8). As described above concerning claim 5, Niwa discloses utilizing outlets located at the bottom of a chamber for withdrawing fluids as shown in Figure 1. Such a configuration is provided in order to utilize the effects of gravity and efficiently remove any unnecessary components away from the packages. Zelina and Niwa do not appear to disclose nozzles in the top portion of a heating area for introducing hot sterile air or a second control unit for regulating the temperature of the hot sterile air introduced into the heating zone to heat packages therein to a temperature above a dew point of the sterilizing agent. However, it is conventionally well known in the art of sterilization to utilize nozzles to introduce hot air to heat packages in a heating zone. Shibauchi discloses an apparatus for sterilizing packages comprising a heating zone (10). The reference continues to disclose that the heating zone comprises a nozzle in the top portion of said heating zone (as shown in Figure 1) capable of introducing a hot sterile air wherein the temperature of the hot sterile air introduced into the heating zone is controlled by a specific controlling means that is capable of heating the packages above

a dew point of the sterilizing agent (column 7, lines 41-55). The control means is provided specifically to ensure that said packages do not contain a condensed fluid.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zelina in view of Niwa to include a nozzle in the top portion of said heating zone capable of introducing a hot sterile air wherein the temperature of the hot sterile air introduced into the heating zone is controlled by a specific controlling means that is capable of heating the packages above a dew point of the sterilizing agent as exemplified by Shibauchi.

9. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (U.S. Publication No. 2002/0159915) in view of Watling et al. (U.K. Patent Application No. GB 2354443 A) as applied to claim 19 above, and further in view of Robinson (U.S. Patent No. 3,891,779)

Zelina in view of Watling does not appear to disclose that nozzles are arranged to introduce sterile air in a top portion of the filling zone. Robinson discloses a device for the sterilization of packages including a filling zone. The reference continues to disclose that the filling zone is provided with nozzles arranged to introduce sterile air in a top portion of the filling zone; and outlets in a bottom portion of the filling zone for withdrawing the sterile air from the filling zone (Figure 1; column 2, lines 61-68; column 3, lines 1-13). The inlets and outlets are provided in order to remove any unsuspecting microorganisms that may be present near the filling station. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Zelina in view of Watling to include nozzles arranged to introduce sterile air in a top

portion of the filling zone; and outlets in a bottom portion of the filling zone for withdrawing the sterile air from the filling zone in order to remove any unsuspecting microorganisms that may be present near the filling station as exemplified by Robinson.

Response to Arguments

10. Applicant's arguments filed November 13, 2007 have been fully considered but they are not persuasive.

Applicant's principle arguments are:

(a) The Combination of Zelina and GB'443 do not suggest "an ambient temperature sensor located outside of the device for sensing the ambient temperature outside the device," or "a relative humidity sensor for measuring the relative humidity outside the device," as recited in Claim 1.

Zelina discloses a device (as shown in Figure 8) for sterilizing objects wherein the device controls the concentration of hydrogen peroxide added in accordance with concentration measurements, temperature measurements, relative humidity measurements and condensation measurements (paragraph 57). Zelina does not appear to disclose that the temperature and relative humidity measurements are taken outside of the device. GB '443 discloses a device (10) for sterilizing objects wherein the device utilizes temperature and humidity measurements that are located outside the device (as shown in Figure 1), wherein the measurements are used to control the concentration of the sterilant (as disclosed in the abstract) and the condensation inside the device. More specifically, the device measures the humidity and temperature at an

area outside of the device. Those measurements determine whether a gas goes through a first or second branch in order to deactivate or receive more sterilant as disclosed in the abstract. Therefore, the measurements are used for controlling the concentration of sterilant added to the device. Additionally, ambient temperature is a common term used to describe room temperature. Evidence is provided by McAffer et al. (U.S. Publication No. 2003/0103864) in paragraph 19. McAffer discloses, "By reference to ambient temperature is generally meant reference to room temperature." Therefore, a temperature sensor that is capable of sensing room temperature meets the limitations of the claim. The heaters (as shown in Figure 1) of GB '443 are in a position that provides enough distance between itself and the temperature sensor (14) that the temperature of the fluid is fully capable of being at an ambient temperature. Therefore, the temperature sensor of GB '443 is an ambient temperature sensor.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McAffer et al. (U.S. Publication No. 2003/0103864) provides evidence that ambient temperature is a common term for room temperature in paragraph 19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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